Remarks/Arguments

This amendment is in response to the Office Action dated April 15, 2008.

Claims 1, 2, 4, 5, 11, 14 and 15-19 remain in this application. Amendments to claims 1 and 11 find support in existing claim 16. New claims 20 - 24 have been added and find support at page 4, lines 32-34 for Claim 20; existing claims 1, 14 and 16 for Claim 21, page 8, lines 31-32 for Claims 22 and 23 and existing claim 16 for Claim 24.

Claims 1, 11 and 16 have been rejected under 35 USC 112 second paragraph for lack of sufficient antecedent basis. Claims 1, 11 and 16 have been amended to make clear the device is designed to be attached to **an** upstream component.

Claims 1, 2, 16-19 have been rejected under 35 USC 102(b) by Mackal (US 2859932).

Applicants disagree. As the standard for anticipation is one of strict identity and "the reference must teach every aspect of the claimed invention either explicitly or inherently" (MPEP section 706.02IV, lines 6 and 7) and the cited reference has failed to teach several of the claimed elements, this reference is not and cannot be an anticipatory reference. As such, the rejection based on 35 USC 102(b) is respectfully requested to be withdrawn as it fails to provide a reference which contains all of the claimed elements of the present claims and therefore no basis for rejection under 35 USC 102 has been properly made.

Mackal relates to a flexible elastomeric valve (PVC is preferred) (column 2, line 58 "are made of elastic plastic material".... and Column 5, lines 11-12 "molded from polyvinyl chloride which is relatively soft and elastic".....). The plastic it discloses is not taught or suggested to be steam sterilizable. Moreover, at Column 5, lines 55-57 it admits it is not a sterile system as it can be pulled apart to remove **foreign matter** that has entered the valve.

Moreover, the plunger 15 of the reference has an outer dimension, at several if not all locations, that is equal to or greater than that of the bore in which it resides so that it creates a slidable friction fit between the plunger and the bore wall. (Column 5, lines 20-39) or the hollow stem of the plunger and the wall of the opening 13 (Column 4, lines 19-25), etc . The present claims require the plunger has a diameter less than that of the bore.

The office action alleges the existence of a cam and cam slot, yet Applicants cannot find any such features disclosed in the reference. At best the reference teaches the use of a shoulder 26 that can in one position but against a rib 37 to limit its travel to some degree. However, no cam and cam slot is taught and the office action fails to point out where such elements reside in the teachings of the reference. To the extent that the Examiner believes they exist, Applicants ask they be directed specifically to where these elements are taught and exactly what reference numbers they relate to.

Lastly the claims require the use of a handle and no such handle is taught by the reference. Element 22 is described by the reference as a "hollow stem 22 which has sealing but sliding contact with the wall of the opening 13..." (Column 4, lines 19-25). Applicants contend no handle as that term is commonly used and know is taught by the reference.

Claims 4, 5 and 11 have been rejected under 35 USC 103(a) over Mackal in view of Tessman et al (US 6210372). Applicants disagree.

The office action argues it would have been obvious to form the device of Mackal using a thermoplastic such as polyetherimide so the device could withstand sterilization.

Mackal uses a soft elastic material. This is done so that the two elements can be molded separately and then assembled together by "temporarily deforming them, the parts then resuming their normal relaxed shape...." (Column 2, 44-45) and see Column 5, lines 40-58. Moreover, it relies

on the soft elastic material of the body and plunger to let its two elements have a slidable friction fit between each other in order to form a seal. Given the clear and unambiguous teachings of Mackal as to nature of the material that must be used in the manufacture of its device so that it can be assembled and so it can create the frictional sliding seal between them, one of ordinary skill in the art would not have thought to substititute a hard, rigid plastic such as polyetherimide for both the plunger and body of Mackal as one would not be able to make or assemble the product as taught by Mackal nor achieve the slidable friction seal between the elements that Mackal requires.

As such the reference fails to suggest the present invention and the prima facie case of obviousness has not been established or if established has been successfully rebutted above.

Claim 14 has been rejected under 35 USC 103(a) by Mackal (US 2,859,932) in view of Leason et al (US 5360413).

Applicants disagree.

It is argued in the office action that Leason teaches a sanitary flange 25 and it would have been obvious to use that flange on Mackal to attach it to a component without contamination. Yet Leason does not teach a flange being capable of attaching to an upstream element. Instead it has a flange that is exposed (which leads to contamination and is at best aseptic but never sterile) and a displacable portion in that flange that when contacted with a syringe or similar device pushes in that portion exposing it to the interior of the syringe.

Mackal is designed and taught as being sealed about its middle portion to a surface of the device to which it is attached. Mackal uses a flange 16 at that point that is heat bonded to the material of the device to which it is attached (a blow up toy for example). Moreover as mentioned

above Mackal does not care about contamination as it teaches to simply take the valve apart and clean out the foreign matter from it and then reassemble it.

There is no teaching, suggestion or motivation to use an exposed unconnected flange of Leason in the device of Mackal. Moreover Mackal isn't worried about contamination and faces that issue by simply taking the device apart and cleaning it. There is no motivation in Mackal to use the flange of Leason as alleged in the office action. As such the prima facie case of obviousness has been successfully rebutted.

Claim 15 has been rejected under 35 USC 103(a) by Mackal (US 2,859,932) in view of Tessman and Leason et al (US 5360413).

Applicants disagree.

As stated above, Mackal relies on the use of the soft elastic material for its assemble and sliding seal. There is no teaching, suggestion or motivation to eliminate such a material and use instead a rigid plastic. Even more so as stated above as to Claim 14 there is no motivation to further compound this issue by using the exposed flange of Leason in which a syringe or similar device is temprorayily inserted. The flange of Leason is not used to attach the first face to a upstream component as claimed and the claim would not have been obvious to one of ordinary skill in the art from the cited combination.

New claims 20-24 are also neither taught nor rendered obvious from the cited prior art fro the same reasons stated above in relation to the other existing claims.

Reconsideration and allowance of the claims is respectfully requested in view of the foregoing amendments and remarks.

Respectfully submitted,

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